Complete Summary

GUIDELINE TITLE

Rituximab for the treatment of follicular lymphoma.

BIBLIOGRAPHIC SOURCE(S)

National Institute for Health and Clinical Excellence (NICE). Rituximab for the treatment of follicular lymphoma. London (UK): National Institute for Health and Clinical Excellence (NICE); 2006 Sep. 20 p. (Technology appraisal guidance; no. 110).

GUIDELINE STATUS

This is the current release of the guideline.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- September 11, 2008, Rituxan (Rituximab): Genentech informed healthcare professionals of revisions to prescribing information for Rituxan regarding a case of progressive multifocal leukoencephalopathy (PML) leading to death in a patient with rheumatoid arthritis who received Rituxan in a long-term safety extension clinical study.

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

Stage III and IV follicular non-Hodgkin's lymphoma

GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness
Treatment

CLINICAL SPECIALTY

Internal Medicine
Oncology

INTENDED USERS

Advanced Practice Nurses
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To evaluate the clinical effectiveness and cost-effectiveness of rituximab for the treatment of stage III and IV follicular lymphoma

TARGET POPULATION

Previously untreated patients with stage III and IV follicular lymphoma

INTERVENTIONS AND PRACTICES CONSIDERED

Rituximab in combination with cyclophosphamide, vincristine, and prednisolone (R-CVP regimen)

MAJOR OUTCOMES CONSIDERED

- Clinical effectiveness
    - Time to treatment failure
    - Tumour response
    - Duration of response
    - Overall survival
    - Disease-free survival
    - Adverse events
    - Health related quality of life
- Cost-effectiveness

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Clinical Excellence (NICE) commissioned an independent academic centre to perform an assessment of the manufacturer's submission on the technology considered in this appraisal and prepare an Evidence Review Group (ERG) report The ERG report for this technology appraisal was prepared by the Liverpool Reviews and Implementation Group, University of Liverpool (see the "Availability of Companion Documents" field).

Clinical Effectiveness

Critique of Company's Approach

Key aspects of the methodological quality of the company's review of the clinical literature was quality assessed based on an accepted quality assessment tool and the results are summarised in Table 3.3.1 of the ERG Report (see "Availability of Companion Documents" field).

Search Strategy

The literature search appears appropriate and comprehensive but insufficient detail was provided to allow the ERG to replicate the search. The ERG conducted searches which confirm the company's finding of only one relevant trial.

Inclusion and Exclusion Criteria Used in the Study Selection

Scope of the Appraisal

- **Population** (clinical effectiveness and cost-effectiveness):

  Adults with stage III/IV non-Hodgkin's follicular lymphoma who have not received any previous treatment

- **Intervention** (clinical effectiveness and cost-effectiveness):

  Rituximab in combination with CVP (cyclophosphamide, vincristine and prednisolone)

- **Comparators** (clinical effectiveness and cost-effectiveness):
  - CVP
  - CHOP (cyclophosphamide, doxorubicin, vincristine and prednisolone)

    - CNOP (cyclophosphamide, mitoxantrone, vincristine and prednisolone)
    - MCP (mitoxantrone, chlorambucil, and prednisolone)
    - Chlorambucil
- **Outcomes** (clinical effectiveness):
    - Time to treatment failure
    - Tumour response (complete response, unconfirmed complete response, partial response, progressive disease)
    - Duration of response
    - Overall survival
    - Disease-free survival
    - Adverse effects of treatment
    - Health related quality of life
- **Outcomes** (cost-effectiveness):

  Incremental cost per quality adjusted life year

  From the draft scope: Details of the time horizon for the economic evaluation based on the time period over which costs and benefits can reasonably be expected given the progression of the disease.

- **Study design** (clinical effectiveness):

  Randomised controlled trial (RCT)

- **Study design** (cost-effectiveness):

  Economic analyses

- **Inclusion criteria** (clinical effectiveness):
    - Main focus of follicular lymphoma
    - Clinical trial data publications
- **Inclusion criteria** (cost-effectiveness):
    - Main focus of follicular lymphoma
    - Full economic evaluation
- **Exclusion criteria** (clinical effectiveness):
    - Clinical trials in previously-treated patients
    - Reviews
    - Animal studies or in vitro research work
- **Exclusion criteria** (cost-effectiveness):
    - No attempt to synthesise costs and benefits
    - Letters, editorials, commentaries or methodological papers

Details of the process used to apply the inclusion criteria were not provided (e.g. the number of people involved in the process and whether this was done independently). It is stated that the titles and abstracts of all references retrieved through literature searches were reviewed and eliminated manually if they were not relevant to the review.

A flow diagram included in the submission indicates that of the 303 references identified in total, 293 were excluded. An additional two references that were

known to the reviewers but not identified during electronic searching were included for consideration in the review.

Economic Evaluation

Identification and Description of Studies

Insufficient detail of the search strategy as reported in the submission meant that the ERG was unable to replicate the economic literature search. However, key terms used and databases searched were described. In addition, the number of papers initially found, and the number of papers excluded, were not reported.

Stated inclusion criteria were:

- **Date of publication**

  Studies published after January 1st 1996 were included.

- **Language of publication**

  Only studies published in English or where English translations were available were included in the systematic review with one exception.

- **Type of study and outcome measure**

  Studies were included if they described an economic evaluation quantifying both costs and benefits (full economic evaluation).

- **Intervention**

  Studies that evaluated the first line treatment of follicular lymphoma with rituximab were included. However, considering that this is a new treatment option and due to the lack of available evidence, studies that evaluated the use of rituximab in relapsed or recurrent follicular lymphoma were also included as well as some studies on aggressive lymphoma.

- **Subjects**

  Studies examining patients with stage III/IV, relapsed and recurrent follicular lymphoma as well as some studies that examined aggressive lymphoma were included. No restrictions were placed on the age or gender of patients included in the analysis. Economic evaluations conducted on patients with different levels of disease severity were also included if they assessed cost-effectiveness in a subgroup of patients with early disease.

NUMBER OF SOURCE DOCUMENTS

Clinical Effectiveness

One multi-centre, open-label trial involving 322 patients was included in the review.

Cost Effectiveness

The company identified 15 papers for inclusion and subsequent data extraction. However, upon closer inspection the Evidence Review Group (ERG) found that only eight of the 15 studies fulfilled the inclusion criteria of assessing both costs and benefits (Table 4.1 of the ERG Report [see the "Availability of Companion Documents" field]). Furthermore, two studies did not include rituximab either alone or in combination. This conflicts with the company's inclusion criteria. It is also worth noting that none of the 15 studies were of R-CVP (rituximab, cyclophosphamide, vincristine, and prednisolone) versus CVP (cyclophosphamide, vincristine, and prednisolone). Although this fact does not conflict with the inclusion/exclusion criteria outlined in the review, it does limit its relevance.

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Clinical Excellence (NICE) commissioned an independent academic centre to perform an assessment of the manufacturer's submission on the technology considered in this appraisal and prepare an Evidence Review Group (ERG) report The ERG report for this technology appraisal was prepared by the Liverpool Reviews and Implementation Group, University of Liverpool (see the "Availability of Companion Documents" field).

Clinical Effectiveness

Validity Assessment of Included Studies

No formal methodological quality assessment of included trials was reported.

Data Extraction

Details of the data extraction process (e.g. number of reviewers and whether data were extracted independently) are not provided in the submission.

Combination of Studies

A meta-analysis was not undertaken by the company as there is only one trial included in the review. However, the submission reports preliminary results of a meta-analysis (available as a conference abstract) that compares survival in patients receiving chemotherapy with or without rituximab for the first-line treatment of follicular or mantle cell lymphoma.

Quality Assessment of Included Study

The company submission did not include a formal quality assessment, or discuss the methodological limitations of the trial. However, the submission provides information concerning certain aspects of the methodological quality of the included trial including the randomisation procedure and the adequacy of follow up.

Issues related to concealment of allocation are not directly addressed; but, as the randomisation process was performed centrally, it is likely that allocation concealment was adequate. Baseline characteristics (as reported in the published paper) were generally comparable in each treatment arm.

It is stated in the submission that the participants were not blinded to treatment allocation and that the nature of treatment made effective blinding of investigators impractical. However, a blinded and independent Critical Events Committee (CEC) was used to review the radiographic scans to avoid observer bias. The number of, and reasons for, withdrawals are reported in both sources.

Economic Evaluation

Data Extraction

The company extracted data from the 15 papers included in the review. Aim of the study, study results, and relevance to decision making in England and Wales were reported. This data extraction is simplistic and does not go into sufficient depth and the data extraction tables were not accompanied by a commentary. However, given that none of the papers compared R-CVP (rituximab, cyclophosphamide, vincristine, and prednisolone) to CVP (cyclophosphamide, vincristine, and prednisolone) these studies are not directly comparable with the economic evaluation presented in the company submission.

Quality Assessment

The submission states that descriptions of any shortcomings in the included papers will be reported. However, it is not clear from the data extraction table if this has been carried out. No formal quality assessment of the included papers appears to have been conducted.

Summary and Conclusions

No economic evaluations are available for R-CVP versus CVP, although this is not explicitly stated by the company. Only eight of the included studies actually met the criteria of full economic analysis (i.e. including both costs and benefits).

The data extraction of the economic literature undertaken by the company was lacking in depth, and provided no quality assessment of the included studies. However, given the fact that these studies do not compare the same healthcare technologies as the company's own economic evaluation, this is of limited importance.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Considerations

Technology appraisal recommendations are based on a review of clinical and economic evidence.

Technology Appraisal Process

The National Institute for Health and Clinical Excellence (NICE) invites 'consultee' and 'commentator' organisations to take part in the appraisal process. Consultee organisations include national groups representing patients and carers, the bodies representing health professionals, and the manufacturers of the technology under review. Consultees are invited to submit evidence during the appraisal and to comment on the appraisal documents.

Commentator organisations include manufacturers of the products with which the technology is being compared, the National Health Service (NHS) Quality Improvement Scotland and research groups working in the area. They can comment on the evidence and other documents but are not asked to submit evidence themselves.

NICE then commissions an independent academic centre to review published evidence on the technology and prepare an 'assessment report'. Consultees and commentators are invited to comment on the report. The assessment report and the comments on it are then drawn together in a document called the evaluation report.

An independent Appraisal Committee then considers the evaluation report. It holds a meeting where it hears direct, spoken evidence from nominated clinical experts, patients and carers. The Committee uses all the evidence to make its first recommendations, in a document called the 'appraisal consultation document' (ACD). NICE sends all the consultees and commentators a copy of this document and posts it on the NICE website. Further comments are invited from everyone taking part.

When the Committee meets again it considers any comments submitted on the ACD; then it prepares its final recommendations in a document called the 'final appraisal determination' (FAD). This is submitted to NICE for approval.

Consultees have a chance to appeal against the final recommendations in the FAD. If there are no appeals, the final recommendations become the basis of the guidance that NICE issues.

Who is on the Appraisal Committee?

NICE technology appraisal recommendations are prepared by an independent committee. This includes health professionals working in the NHS and people who are familiar with the issues affecting patients and carers. Although the Appraisal Committee seeks the views of organisations representing health professionals, patients, carers, manufacturers and government, its advice is independent of any vested interests.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

The Committee discussed the assumptions in the manufacturer's economic model, and noted that the age of the patients in the economic model reflected the median age of the patients in the registration study. They heard from the Evidence Review Group (ERG) that this was relatively younger than the age of patients with lymphoma typically receiving chemotherapy in England and Wales, and that this may underestimate the cost per quality-adjusted life year (QALY) gained because death rates from causes other than lymphoma would be higher for an older population than for a younger population. The Committee was also mindful that this effect may be further exacerbated both by the way in which mortality was incorporated in the model and by the use of utility values which remain constant regardless of age. The Committee examined analyses undertaken by the ERG using the manufacturer's model which adjusted the age of the patient cohort and the way in which mortality was included. These analyses suggested that the estimates of the cost per QALY gained remained below 20,000 pounds sterling regardless of the age cohort. However, while acknowledging that this additional analysis helped to reduce uncertainty, the Committee believed the estimates should be interpreted with some caution, as the model structure did not separate the risk of death from lymphoma from death from other causes, and the utility estimates may not accurately reflect the health-related quality of life of patients with follicular lymphoma.

The Committee considered the assumption in the manufacturer's economic model that gains in progression-free survival translated into gains in overall survival. The Committee considered evidence from studies of CVP (cyclophosphamide, vincristine, and prednisolone) with and without rituximab, and CHOP (cyclophosphamide, doxorubicin, vincristine, and prednisolone) with and without rituximab, which demonstrated that gains in progression-free survival did in part translate into gains in overall survival. This was also supported by clinical opinion. In addition, the ERG analyses suggested that only when the increase in

progression-free survival did not translate into any incremental gain in survival did the cost per QALY gained rise above 20,000 pounds sterling. The Committee was of the opinion that, based on the evidence available, it was likely that gains in progression-free survival would translate at least partially into a gain in overall survival. They were therefore satisfied that although this remained an area of uncertainty, it did not in itself lead to increases in the estimates of cost per QALY gained that were incompatible with the best use of National Health Service (NHS) resources.

The Committee was aware of additional uncertainties in the model which may also have underestimated the cost per QALY gained. Particular concern was noted about the exclusion of the costs and consequences of receiving rituximab as a last-line therapy, and the exclusion from the economic model of adverse events which, although not occurring at a rate which was statistically significant, occurred with greater frequency in the rituximab plus CVP arm in the clinical trial. The Committee believed this latter concern could underestimate the costs and overestimate the QALYs associated with rituximab plus CVP treatment. In addition the Committee raised concerns about the source and reliability of the cost data for the progressed health state, which could also underestimate the cost per QALY gained. However, the Committee was also aware that the assumption in the model that all patients received 8 treatment cycles may overestimate the cost per QALY gained, as some patients may have treatment withdrawn if they experienced an adverse event or lack of response, and in clinical practice six cycles may be given instead of eight.

The Committee accepted that the economic modelling provided by the manufacturer was associated with a number of uncertainties as a result of the structure and assumptions made in the model. They were aware that not all of these could be adjusted by the ERG, but that the group's analyses had helped to explore uncertainties around the estimates of cost effectiveness. Although the Committee acknowledged that in some respects the assumptions in the model (such as 8 treatment cycles for every patient) could overestimate the cost per QALY gained, overall the Committee was mindful of the possibility that the manufacturer's economic model underestimated the cost per QALY gained of adding rituximab to CVP.

Committee was of the opinion that the manufacturer had presented evidence most strongly for the use of rituximab plus CVP where CVP would otherwise have been the preferred treatment option, but that greater uncertainty existed where chlorambucil or CHOP would have been the preferred treatment option. However, the Committee considered that, on balance, rituximab in combination with CVP had been demonstrated to be a cost-effective use of NHS resources.

METHOD OF GUIDELINE VALIDATION

External Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Consultee organizations from the following groups were invited to comment on the draft scope, Assessment Report and the Appraisal Consultation Document

(ACD) and were provided with the opportunity to appeal against the Final Appraisal Determination.

- Manufacturer/sponsors
- Professional/specialist and patient/carer groups
- Commentator organisations (without the right of appeal)

In addition, individuals selected from clinical expert and patient advocate nominations from the professional/specialist and patient/carer groups were also invited to comment on the ACD.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Rituximab within its licensed indication (that is, in combination with cyclophosphamide, vincristine, and prednisolone) is recommended as an option for the treatment of symptomatic stage III and IV follicular lymphoma in previously untreated patients.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting the recommendations is not specifically stated.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate use of rituximab for the treatment of stage III and IV follicular lymphoma

POTENTIAL HARMS

Rituximab is associated with infusion-related reactions including severe cytokine release syndrome and hypersensitivity. Both typically occur within 2 hours of the first administration and are characterised by severe dyspnoea together with fever, chills, rigors, urticaria and angioedema. Full blood cell counts should be performed regularly, as rituximab in combination with cyclophosphamide, vincristine and prednisolone (CVP) has also been associated with worse neutropenia than CVP alone.

For full details of side effects and contraindications, see the summary of product characteristics (SPC) available at http://emc.medicines.org.uk/.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

This guidance represents the view of the Institute, which was arrived at after careful consideration of the available evidence. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. The guidance does not, however, override the individual responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

- The Healthcare Commission assesses the performance of National Health Service (NHS) organisations in meeting core and developmental standards set by the Department of Health in "Standards for better health" issued in July 2004. The Secretary of State has directed that the NHS provides funding and resources for medicines and treatments that have been recommended by National Institute for Health and Clinical Excellence (NICE) technology appraisals normally within 3 months from the date that NICE publishes the guidance. Core standard C5 states that healthcare organisations should ensure they conform to NICE technology appraisals.
- "Healthcare standards for Wales" was issued by the Welsh Assembly Government in May 2005 and provides a framework both for self-assessment by healthcare organizations and for external review and investigation by Healthcare Inspectorate Wales. Standard 12a requires healthcare organisations to ensure that patients and service users are provided with effective treatment and care that conforms to NICE technology appraisal guidance. The Assembly Minister for Health and Social Services issued a Direction in October 2003 which requires Local Health Boards and NHS Trusts to make funding available to enable the implementation of NICE technology appraisal guidance, normally within 3 months.
- NICE has developed tools to help organisations implement this guidance (listed below). These are available on NICE website (http://guidance.nice.org.uk/TA37) (see also the "Availability of Companion Documents" field).
    - Local costing template incorporating a costing report to estimate the savings and costs associated with implementation
    - Audit criteria to monitor local practice

IMPLEMENTATION TOOLS

Audit Criteria/Indicators
Patient Resources
Quick Reference Guides/Physician Guides
Resources

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

National Institute for Health and Clinical Excellence (NICE). Rituximab for the treatment of follicular lymphoma. London (UK): National Institute for Health and Clinical Excellence (NICE); 2006 Sep. 20 p. (Technology appraisal guidance; no. 110).

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2006 Sep

GUIDELINE DEVELOPER(S)

National Institute for Health and Clinical Excellence (NICE) - National Government Agency [Non-U.S.]

SOURCE(S) OF FUNDING

National Institute for Health and Clinical Excellence (NICE)

GUIDELINE COMMITTEE

Appraisal Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that appraisal.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) format from the National Institute for Health and Clinical Excellence (NICE) Web site.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Rituximab for the treatment of follicular lymphoma. Quick reference guide. London (UK): National Institute for Health and Clinical Excellence (NICE);

2006 Sep. 2 p. (Technology appraisal 110). Available in Portable Document Format (PDF) from the National Institute for Health and Clinical Excellence (NICE) Web site.

- Costing template and report: rituximab for the treatment of follicular lymphoma. London (UK): National Institute for Health and Clinical Excellence (NICE); 2006 Sep. Various p. (Technology appraisal 110). Available in Portable Document Format (PDF) from the NICE Web site.
- Rituximab for the treatment of follicular lymphoma. Audit criteria. London (UK): National Institute for Health and Clinical Excellence (NICE); 2006 Sep. 8 p. (Technology appraisal 110). Available in Portable Document Format (PDF) from the NICE Web site.
- Rituximab for the first line treatment of stage III-IV follicular non-Hodgkin's lymphoma. Evidence Review Group Report. Liverpool Reviews and Implementation Group, Liverpool, UK. 2006 Apr 4. 54 p. Electronic copies: Available from the NICE Web site.

Print copies: Available from the National Health Service (NHS) Response Line 0870 1555 455. ref: N1124. 11 Strand, London, WC2N 5HR.

PATIENT RESOURCES

The following is available:

- Rituximab for the treatment of follicular lymphoma. Understanding NICE guidance - Information for people who use NHS services. London (UK): National Institute for Health and Clinical Excellence (NICE); 2006 Sep. 5 p. (Technology appraisal 110).

Electronic copies: Available in Portable Document Format (PDF) from the National Institute for Health and Clinical Excellence (NICE) Web site.

Print copies: Available from the NHS Response Line 0870 1555 455. ref: N1125. 11 Strand, London, WC2N 5HR.

NGC STATUS

This NGC summary was completed by ECRI Institute on August 6, 2007. This summary was updated by ECRI Institute on October 8, 2008 following the U.S. Food and Drug Administration advisory on Rituxan (rituximab).

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